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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/519,162 | 08/15/2005 | Kazuo Umezawa | 09707.0001 | 4831 |

22852 7590 12/13/2007

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| EXAMINER | |
|---|---|
| TEALE, MICHAEL J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1614 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 12/13/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/519,162 | UMEZAWA ET AL. | |
| | Examiner | Art Unit | |
| | Michael J. Teale Ph.D. | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26 and 29-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26 and 29-34* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-12, and 20 are drawn to a method of improving at least one symptom resulting from a tumor cell administering compounds of formula (1).

Group II, claims 13-18 are drawn to a method of enhancing the effect of a therapy administering compounds of formula (1).

Group III, claim 19 is drawn to a method of inhibiting proliferation of a tumor cell administering compounds of formula (1).

Group IV, claims 21 and 22 are drawn to method of suppressing the expression of an adhesion molecule administering compounds of formula (1).

Group V, claims 23 and 24 are drawn to method of inducing apoptosis in a tumor cell administering compounds of formula (1).

Group VI, claims 25 and 26 are drawn to a method of improving or inhibiting arteriosclerosis administering a NF-κB inhibitor.

Group VII, claim 29 is drawn to a method of preventing or inhibiting cancer matastasis administering a NF-κB inhibitor.

Group VIII, claim 30-33 are drawn to a method of alleviating or inhibiting cachexia administering compounds of formula (1).

Group IX, claims 34 is drawn to a method of alleviating or inhibiting cachexia administering a NF-κB inhibitor.

The inventions listed in Groups I to IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: the compounds of formula (1) encompass numerous different structures, that when administered to a mammal will have different modes of operation and effect numerous biological systems differently. For example a compound of formula (1) may not be NF-κB inhibitor and thus effect a completely different biochemical system than a NF-κB inhibitor would effect. The methods of treating cancer in general would require many different types of molecules and would depend on the type of cancer being treated and the manner in which the treatment was carried out. For example, one would not give orally a compound that would irritate the intestinal epithelial lining, while another compound used for the same purpose might not irritate the intestine.

***Species Election***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Compounds of formula (1); NF-κB inhibitor; tumor type.

Applicant is required, in reply to this action, to elect a single species by:

Should applicant elect any one of groups I-VI, and VIII, applicant is required to elect a compound of formula (1) by defining each and every formula variable such that a single disclosed compound is elected, or by electing a disclosed specific NF-κB inhibitor (for example claim 25), as well as a type of tumor (e.g. disclose what type of cancer the tumor comes from, for example breast cancer, lung cancer),

Should applicant elect Group VII, applicant is required to elect a type of cancer, as well as, a disclosed, specific NF-κB inhibitor,

Should applicant elect Group IX, applicant is required to elect a disclosed, specific NF-κB inhibitor,

to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Compounds of formula (1): claims 1-26, and 30-33; NF-κB inhibitors claims 25, 29 and 34, cancer type: claim 29.

The following claim(s) are generic: claims 1-26, and 29-34.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the compounds of formula (1) represent numerous different compounds having different structures, modes of operation and effects on biochemical systems. The NF-κB inhibitors may be anything that inhibits NF-κB including proteins, compounds of all classes, and nucleic acids all of which represent vastly different structures, modes of operation and effects. Cancer types may be any cancer which stem from all types of tissue having vastly different charateristics.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is cautioned that election of a compound of formula (1) or NF-κB inhibitor which is not itself as elected specifically disclosed as filed may be considered New Matter.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. Furthermore the examiner may find if necessary to further restrict the elected invention once depending on applicant's election and the state of the associated art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Teale Ph.D. whose telephone number is (517)-272-6897. The examiner can normally be reached on 7:30 am to 4:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ardin H. Marschel 12/9/07

MJT

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER